REMARKS

Provisional Election:

Further to the restriction and election of species requirements discussed in detail below, Applicant provisionally elects **with traverse** the invention of Group I, claims 1-3 and 14-15, more particularly the embodiment wherein the mutated polypeptide derived from the pollen allergen Phl p7 has the amino acid sequence set forth in SEQ ID NO: 6. Applicants respectfully submit that claims 1-3 and 14-15 read on the elected species. However, Applicants request reconsideration of the restriction requirement on the grounds that examination of the entirety of the claims would not constitute an undue burden.

Restriction:

In the Office Action of December 10, 2007, the Examiner indicates that restriction is required under 35 U.S.C. §§ 121 and 372. With regard to the latter, the Examiner indicates that the instant application contains claims to the following inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

- Group I: claims 1-3 and 14-15, drawn to a mutated polypeptide derived from the pollen allergen Ph1 p7, a pharmaceutical composition and a kit thereof;
- Group II: claims 4-8, drawn to a polynucleotide encoding the mutated polypeptide of Ph1 p7, a vector containing the polypeptide, a host cell transformed with the vector, and a method of preparing the Phl p7 polypeptide; and
- Group III: claims 16-19, drawn to a method of treating and/or preventing an allergic disorder comprising administering to a patient in need thereof an effective amount of a mutated polypeptide derived from the pollen allergen Phl p7.

According to the Examiner, the inventions of Groups I – III do not relate to a single general inventive concept because they lack the same or corresponding special technical features. More particularly, the Examiner alleges that the shared features of claim 1 are disclosed by WO 99/34826, which teaches a mutated polypeptide derived from the pollen allergen Phl p7 comprising SEQ ID NOs: 2 and 3, pharmaceutical compositions thereof, and a kit thereof for use in the desensitization

of patients against an allergen by administering MHC Class II restricted peptides of 5 to 50 amino acids in length of the disclosed allergens to patients. The Examiner thus concludes that since the inventions do not contribute a special technical feature when viewed over the prior art, they do not relate to a single general inventive concept and so lack unity of invention. Accordingly, election of a single invention from among Groups I – III is required.

To be deemed fully responsive, Applicants provisionally elect **with traverse** the invention of Group I, claims 1-3 and 14-15. However, Applicants respectfully request reconsideration of the restriction requirement in view of the following remarks.

It is well established that if the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to more than one independent and/or distinct invention. In this case, claims 4-8 and 16-19, corresponding to the inventions of Groups II and III, respectively, either directly or indirectly depend from and thus require all the particulars of claim 1 (Group I). Accordingly, the search required for the elected mutated polypeptide of Group I overlaps with, and indeed is central to, the search required for the non-elected polynucleotides, vectors, host cells, and methods of Groups II and III. Thus, Applicants submit that it would not be an undue burden for the Examiner to search and consider claims 1-8 and 14-19 together in the present application. Accordingly, Applicants respectfully request that the Examiner reconsider the restriction requirement and specifically reconsider examining non-elected claims 4-8 and 16-19 with the elected invention of Group I.

In the event the Examiner maintains the outstanding restriction between a mutated Phl p7 polypeptide (Group I) set forth in claims 1 *et seq.* and methods of making and using such a polypeptide set forth in claims 7-8 (Group II) and 16-19 (Group III), respectively, Applicants retain the right to rejoinder in accordance with the provisions of 37 C.F.R. § 1.104. Accordingly, the examination of non-elected method claims 7-8 and 16-19 should be held in abeyance until the indication of an allowable polypeptide claim.

Election of Species:

In the outstanding Office Action, the Examiner indicates that the instant application contains a number of patentably distinct species, thereby necessitating restriction under 35 U.S.C. § 121. As pertaining to the elected invention of Group I, the Examiner indicates that Applicants must select a single specific Phl p7 polypeptide having a specified defined structure (i.e., one amino acid sequence from among SEQ ID NOs: 2, 3, 4, 5, and 6). Solely to in order to be responsive, Applicants provisionally elect **with traverse** the polypeptide represented by SEQ ID NO: 6. However, Applicants respectfully request reconsideration of the election of species requirement in view of the following remarks.

MPEP 803.02 reads as follows:

> "If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions." (emphasis added)

In a similar fashion, the Administrative Instructions to the PCT, Annex B, in addressing "Markush practice" in part (f), state that when a single claim defines chemical or non-chemical alternatives, the unity of invention requirement for a technical interrelationship and the same or corresponding special technical features shall be considered to be met when the alternatives are "of a similar nature". More particularly, when alternatives share (a) a common property or activity, and (b) a significant structural element or a common structure, they are deemed to be of a similar nature sufficient to demonstrate unity of invention.

In this case, the alternative embodiments set forth in SEQ ID NOs: 2-6 not only share a common property, namely the ability to display reduced allergenic activity as compared to wild-type timothy grass pollen allergen Phl p7, thereby making them useful as allergy vaccines for the treatment of sensitized allergic patients and for prophylactic vaccination, but, in that each of the recited polypeptides is either a fragment or point mutant of the wild-type Phl p7 polypeptide set forth in SEQ ID NO: 1, they also share significant common structure that is essential to this shared activity. More particularly:

- SEQ ID NO: 2, designated in the specification as "peptide 1", is a mutated polypeptide derived from the pollen allergen Phl p7 which corresponds to the first EF hand motif that extends between residues 2 and 37 of SEQ ID NO: 1;
- SEQ ID NO: 3, designated in the specification as "peptide 2", is a mutated polypeptide derived from the pollen allergen Phl p7 which corresponds to the second EF hand motif that extends between residues 36 and 78 of SEQ ID NO: 1;
- SEQ ID NO: 4, designated in the specification as "mutant 1.6", is a mutated polypeptide derived from the pollen allergen Phl p7 which carries two point mutations (E24A and D59A) as compared to the wild-type Phl p7 polypeptide, the amino acid sequence of which is set forth herein at SEQ ID NO: 1;
- SEQ ID NO: 5 designated in the specification as "mutant 2A", is a mutated polypeptide derived from the pollen allergen Phl p7 which carries three point mutations (D17A, E24A, and D59A) as compared to the wild-type Phl p7 polypeptide, the amino acid sequence of which is set forth herein at SEQ ID NO: 1; and
- SEQ ID NO: 6, designated in the specification as "mutant 4", is a mutated polypeptide derived from the pollen allergen Phl p7 which carries four mutations (D17A, E24A, D52A, and E59A) as compared to the wild-type Phl p7 polypeptide, the amino acid sequence of which is set forth herein at SEQ ID NO: 1.

Thus, in that the alternative sequences recited in claim 1 share a common activity as well as significant sequence homology, Applicants respectfully submit that they are so "closely related" or of such a "similar nature" that search and examination of the entire claim is warranted.

In addition, Applicants wish to remind the Examiner of the Directors' *sua sponte* decision to partially waive the requirements of 37 CFR § 1.141 *et seq.* and permit a reasonable number of nucleotide or amino acid sequences to be claimed in a single application "so as to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office". In the context of this decision, it was determined that normally ten sequences would constitute a reasonable number for examination purposes and therefore, in most cases, up to ten independent and distinct sequences could be examined in a single application without restriction.

Thus, while different polypeptides, each defined by unique amino acid sequences, may be presumed to represent independent and distinct inventions and therefore subject to a requirement for restriction, it has been established that examination of up to ten amino acid sequences generally does not constitute an undue burden. In this case, given the related nature of SEQ ID NOs: 2-6 discussed in detail above, Applicants submit that no undue burden would be imposed on the Examiner to conduct a computer search for each of SEQ ID NOs: 2-5 together with elected SEQ ID NO: 6. Accordingly, Applicants respectfully reconsideration and withdrawal of the election of species.

In the event the Examiner maintains the instant election of species requirement, Applicants hold in abeyance the examination of the additional species upon an indication of allowability of the elected species pursuant to M.P.E.P. 803.02. In particular, it is noted that "should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended [to the non-elected species]. . . The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim." M.P.E.P. 803.02.

CONCLUSION

The outstanding Office Action set a one-month shortened statutory period for response, response being due on or before **January 10, 2008**. Thus, Applicants respectfully submit that this response is timely and no fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to our Deposit Account No. 50-2101. If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,

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